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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/866,793 05/30/01 VESPER S VESPER1

001444 HM12/0913
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EXAMINER

SHAHNAN-SHAH, K
ART UNIT PAPER NUMBER

1645
DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/866,793	Applicant(s) VESPER, STEPHEN JOSEPH	
Examiner Khatol S Shahnan-Shah	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 August 2001.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
 - 4a) Of the above claim(s) 1-2 and 6-18 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 3-5 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s) 5.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of August 22, 2001 in Paper No. 4 is acknowledged. The traversal is on the ground(s) that searching for groups I-II and IV-V will not put additional burden upon the office when searching for elected group III, has been noted. This is not found persuasive because while the searches may overlap but they are not coextensive. Because Groups I- II and IV are drawn to different products with specifically and technically distinct features. The claims of group V are drawn to a method of immunization. Those of group III are drawn to a method of in vitro diagnosis which encompass distinct processes and methods.

The requirement is still deemed proper and is therefore made **FINAL**.

In regard to the election of fungal species in elected claim 5, applicant was not responsive in August 22, 2001 response to the restriction. (see interview summary report).

2. Claims 1-2 and 6-18, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected groups I, II, IV and V.
3. Currently claims 3-5 are pending and under consideration.

Specification Informalities

4. The disclosure is objected to because of the following informalities:

Appropriate correction is required.

Specification page 12, paragraph 0044, line 4 the word animal is misspelled.

Specification page 7, paragraph 0028 the abbreviation KLH is used, the full name or explanation of the above abbreviation is required when appears in the specification for the first time.

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Specification page 8, paragraph 0031 the abbreviations ALP, HRP, TMB, BCIP are used, the full name or explanation of the above abbreviations are required when appear in the specification for the first time.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 3 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Stachybotrys chartarum*, does not reasonably provide enablement for other fungal species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/or the invention commensurate in scope with these claims. Enablement is considered in view of the Wands factors (MPEP) 2164.01(a). Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples (6) the quantity of experimentation, (7) the relative skill of those in the art, and (8) the breadth of the claims.

Claim 3 recites a method of detecting hemolysin-producing fungi. The scope of the claim encompass all hemolysin-producing fungi. Claim 5 recites a method of detecting hemolysin producing fungi for a group consisting of: *Stachybotrys chartarum*, *Aspergillus fumigatus*,

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Candida albicans and *Penicillium chrysogenum*. The scope of the claim encompass all of the above fungi. The specification teaches only isolation of *Stachybotrys chartarum* hemolysin (pages 6 and 7) and an ELISA assay for detecting *Stachybotrys chartarum* (page 8). The breadth of the claims are extremely broad, encompassing all hemolysin-producing fungi. The amount of direction or guidance is limited to the isolation and detection of hemolysin only from one fungal species (*Stachybotrys chartarum*). Because of the lack of guidance provided by the specification in regard to other hemolysins isolated from other hemolysin producing fungi, antibody production and their detection methods, it would require undue experimentation by one skilled in the art to make or use the full claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishida et al.

(Annual Report of Tohoku College of Pharmacy, No. 39, pp. 189-194, 1992).

Claims 3-5 are drawn to a method of detecting antigens to fungal hemolysins with labeled (enzyme, chemiluminescent) antibodies to fungal hemolysins.

Ishida et al teach a method of enzyme immunoassay of *Aspergillus* hemolysin by chemiluminescence reaction of Luminal-Peroxidase. They established a chemiluminescence enzyme immunoassay of *Aspergillus* hemolysin in which the enzyme immunoassay was carried out using peroxidase as a label enzyme by the double –antibody sandwich method. The results

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indicated that *Aspergillus* hemolysin could be determined accurately within the range of 10-100 pg by this method.

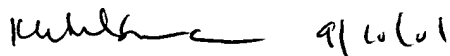
Since the office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e., that the method of prior art does not possess the same material structure and functional characteristics of the claimed method). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

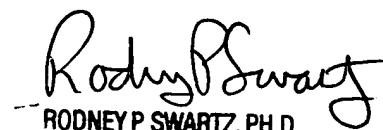
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER